REMARKS

In the Office Action, claim 29 was rejected under 35 USC 112, second paragraph as allegedly indefinite. Claim 26 was rejected under 35 USC 112, second paragraph as allegedly indefinite. Claims 1, 22 and 26-30 were rejected under 35 USC 112, first paragraph as allegedly lacking written description. Claims 1, 22, 23-26, 29 and 30 were rejected under 35 USC 102(b) as allegedly anticipated by Peltola et al. (J Biomed Mater Res, 51:200-208, "Peltola").

Claim 1 has been amended to recite a list of metal ions used in combination with the organometallic titanium oxide precursor as recited in claim 1. Support for the amendment can be found at least at page 11, last paragraph, of the specification. No new matter is added.

Claim 1 is Drawn to a Combination of a Titanium Oxide Precursor and Metal Ions in a Sol

Applicants would like to emphasize that claim 1 involves the use in combination of an organometallic titanium oxide precursor and metal ions as metal salts and/or organometallic compounds in a preparation used to form an anti-microbial or antibacterial coating on an implant. These compounds are formed in a homogeneous distribution throughout a coating layer on the implant by use of a sol, which solubilizes these components in a homogenous manner. Claim 1 has been amended above to emphasize this combination.

The examples demonstrate that, through the use of these techniques, highly antibacterial coatings are formed on implant materials which enormously decrease bacterial colonization. Furthermore, the soluble nature in which the metal ions are incorporated into the coating assures both immediate antibacterial effects, as well as a providing a surface which is compatible with extended uses within the body.

As discussed in the specification (paragraph bridging pages 8-9), prior art copper-containing implants retain their anti-microbial effect throughout their use, resulting in inflammatory reactions and lack of integration.

In contract, the anti-bacterial effect provided by the current invention allows for inhibition of bacterial growth for a time sufficient to permit the slower-growing animal cells to colonize the surface, without providing a prolonged exposure to metal ions that would ultimately prove toxic at the location of implant.

Summary of Telephonic Interview

Applicants thank the Examiner for the courtesy of a brief telephonic interview on Dec. 16, 2009. Applicants discussed the rejections under 35 USC 112, and presented the above argument regarding the combination recited in claim 1. Claim 1 was accordingly amended based on that discussion.

The Rejection of Claim 29

Claim 29 was asserted to be indefinite under 35 USC 112, second paragraph, for allegedly not setting forth positive method steps. This rejection is traversed.

This is a continuation of a prior rejection, in which Claim 29 had been presented during PCT prosecution as a "use" claim of the coated implant, as appropriate under many national patent laws. The prior examiner had objected to this form. Applicants amended the claim to comport with U.S. practice. Claim 29 as amended recites:

> 29. (Previously Presented) A method of implanting a coated implant within a patient, comprising
> providing an implant according to claim 22; and
> implanting the implant within the body of the patient.

Claim 29 thus sets forth two positively recited method steps:

(1) providing an implant according to claim 22; and

(2) implanting the implant within the body of the patient.

This is a clear recitation of how a coated implant is used. The first positively recited step of the claim requires provision of a coated implant, in accordance with claim 22 (and ultimately dependent on the method of claim 1). As the coated implant is a novel product resulting from the novel method of claim 1, the use of such a novel implant is accordingly patentable.

The second positively recited step of the claim requires implantation of that device within the body of the patient. Applicants assert this is the broadest reasonable use of the implant of claim 22, and that they are entitled to pursue claim coverage to such a use.

Furthermore, the Office Action does not clearly state how these two positively recited method steps do not constitute particular method steps rendering the claim indefinite. Applicants are entitled to a clear statement of the grounds of rejection.

Accordingly, as claim 29 sets out positively recited method steps, claim 29 is asserted to be clear and definite. Withdrawal of the rejection of claim 29 is respectfully requested.

The Rejection Under 35 USC 112, First Paragraph

Claims 1, 22 and 26-30 were rejected under 35 USC 112, first paragraph as allegedly lacking written description. This rejection is traversed.

The Office Action asserted that the specification discusses homogeneous distribution of particles in the coating, but not in a sol, as recited in claim 1.

Initially, Applicants note that the language inserted into claim 1 in the prior amendment was obtained directly from dependent claim 15 as filed, and thus the application contained explicit support for that claim language.

Additionally, the specification discusses homogeneous distribution of metal ions both in the coating and in the sol used to form the coating. Page 7, second full paragraph, teaches that "[a] homogeneous distribution of this type can be achieved ... by preparing ... a coating preparation or suspension ... used for the application onto the implant and in which metal ions are dissolved." Page 9, first full paragraph, also discusses the dissolution of metallic compounds in a sol, and discusses coating an implant using such a mixture in a variety of methods at page 9, second full paragraph.

The paragraph bridging pages 13-14 specifically discusses the formation of a coating on an implant using a preparation containing an organic solvent "with metal salts and/or organometallic compounds to distribute metal ions homogeneously in the preparation" (page 14, lines 4-5, emphasis added).

Thus, the specification contains written description support for the homogeneous distribution of metal ions in the sol preparation used to form the coating on the implant, as recited in claim 1. Withdrawal of the rejection of claims 1, 22 and 26-30 under 35 USC 112, first paragraph, is respectfully requested.

The Rejection of Claim 26 Under 35 USC 112, Second Paragraph

Claim 26 was rejected under 35 USC 112, second paragraph as allegedly indefinite. This rejection is traversed.

The Office Action asserted that the claim was indefinite because a coating on an implant must always be biocompatible. This claim language is related to the discussion in the application that prior art devices containing antibacterial metals were useful only for short-term implants, but cause inflammatory reactions under long-term use. Thus, short-term and long-term biocompatibility can differ in metal-coated implants.

The recitation in the claim regarding the coating being later biocompatible relates to the ability of the current invention to provide both an anti-bacterial effect as well as long-term biocompatibility, a combination not found in prior art implants.

For example, the application describes the use in the prior art of silver or silver-containing (anti-bacterial) coatings on short-term implants such as catheters (page 1, second paragraph). However, the undesirability of highly toxic implant surfaces for long-term implants such as hip joint endoprostheses is described at page 2, full paragraph. Additionally, the chronic inflammatory reactions provoked by prior art copper-containing materials rendering them unsuitable for long-term use is discussed in the specification at page 8, last paragraph.

Thus, the language in claim 26 is asserted to be clear and definite when read in the context of the specification, as there is a difference between short-term and long-term biocompatibility, and in the devices used in such settings. Withdrawal of the rejection of claim 26 is therefore respectfully requested.

The Rejections Under 35 USC 102

Claims 1, 22, 23-26, 29 and 30 were rejected under 35 USC 102(b) as allegedly anticipated by Peltola. This rejection is traversed.

Peltola does not teach or suggest the use of a preparation comprising a combination of metal ions and an organometallic titanium oxide precursor homogeneously dispersed in a sol to form one or more coatings on an implant. Peltola deals merely with a timecourse study of the

aging of a sol prior to application, the number of layers applied, and their effect on calcium phosphate formation as a surrogate for their utility in the replacement of damaged bone tissue in orthopedic and dental implants (see abstract).

Peltola thus provides nothing more than what is discussed in the application at page 2, lines 2-5: that sols are known in the art for the preparation of biocompatible titanium oxide coatings.

As the cited art does not teach or suggest all the claim limitations of claim 1, and thus all claims as they are ultimately dependent on claim 1, anticipation by Peltola has not been established. Withdrawal of the rejection under 35 USC 102 is respectfully requested.

CONCLUSION

CONDITIONAL REQUEST FOR TELEPHONIC INTERVIEW

Applicants respectfully submit that the claims are in condition for allowance. Should any issues remain after consideration of the above, the Examiner is requested to contact the undersigned at 858-228-7829 prior to the issuance of a subsequent action.

Respectfully submitted,

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